DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 1, 2014

NEOLOGICA S.R.L.
MARCO SAMBIN
STRADA VILLE, 58
17014 CAIRO MONTENOTTE (SV)
ITALY

Re: K141061
Trade/Device Name: RemotEye Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 16, 2014
Received: July 21, 2014

Dear Mr. Sambin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141061

Device Name
RemotEye Viewer

Indications for Use *(Describe)*
The RemotEye Viewer software product is intended to be used as a fully functional, web-based medical image viewer to download, review, interpret, manipulate, visualize and print medical multi-modality image data in DICOM format, also stored in remote locations with respect to the viewing site. When interpreted by a trained physician, the medical images displayed by RemotEye Viewer can be used as an element for diagnosis.
Typical users of RemotEye Viewer are trained professionals, including but not limited to radiologists, physicians, nurses and technicians.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

005_AI 510(k) Summary of Safety and Effectiveness

Date Prepared: April 15, 2014
Date of Additional Information: July 16, 2014

Submitter's Name: NeoLogica s.r.l.
Submitter's Address: Strada Ville, 58 - 17014 - Cairo Montenotte (SV) - Italy
Submitter's Phone Number: +39 019 505314
Submitter's E-mail: info@neologica.it
Submitter's Website: www.neologica.it

Establishment Registration Name: NEOLOGICA S.R.L.
Establishment Registration Number: 3005202320

Contact person's Name: Marco Sambin
Contact person's Title: Director
Contact person's Phone Number: +39 019 505314
Contact person's E-mail: marco.sambin@neologica.it

Device Common Name: DICOM-compliant medical image viewer
Device Trade Name: RemotEye Viewer
Device Classification Name: System, Image Processing, Radiological
Device Regulation Description: Picture archiving and communications system
Device Regulation Medical Specialty: Radiology
Device Review Panel: Radiology
Product Code: LLZ
Device Regulation Number: 892.2050
Device Class: II
Device 510(k) Number: K141061

Predicate Device: eFilm Workstation
Predicate Device Original Applicant: eFilm Medical, Inc. - 500 University Ave., Suite 300, Toronto, Ontario Canada M5G 1V7
Predicate Device 510(k) Number: K012211
Predicate Device Classification Name: System, Image Processing, Radiological
Predicate Device Regulation Description: Picture archiving and communications system
Predicate Device Classification Advisory Committee: Radiology

Predicate Device Review Advisory Committee: Radiology

Predicate Device Product Code: LLZ

Predicate Device Regulation Number: 892.2050

Predicate Device Class: II

Date Received: 07/16/2001

Decision Date: 07/31/2001

Decision: Substantially Equivalent (SE)

Device Description

The RemotEye Viewer software product is a feature-rich, diagnostic-level, web-based DICOM medical image viewer that allows downloading, reviewing, interpreting, manipulating, visualizing and printing medical multi-modality image data in DICOM format, from a client machine. The DICOM images may be physically remote with respect to the viewing client, but reachable through a network.

Typical users of RemotEye Viewer are trained professionals, including but not limited to radiologists, physicians, nurses and technicians.

Device Intended Use

The RemotEye Viewer software product is intended to be used as a fully functional, web-based medical image viewer to download, review, interpret, manipulate, visualize and print medical multi-modality image data in DICOM format, also stored in remote locations with respect to the viewing site. When interpreted by a trained physician, the medical images displayed by RemotEye Viewer can be used as an element for diagnosis.

Typical users of RemotEye Viewer are trained professionals, including but not limited to radiologists, physicians, nurses and technicians.

Technological Characteristics

Both the RemotEye Viewer and the eFilm Workstation are stand-alone medical imaging software packages which can be used on more than one hardware platform. As long as minimum requirements are met, the user is free to choose his/her own hardware platform. Hardware and software requirements for RemotEye Viewer are described both in the Installation Manual and in the User Manual. Please refer to pages 008_AI - 4, 008_AI - 5, *008_AI - 15*, *008_AI - 16* of the *008_AI RemotEye Viewer Installation Manual* and pages *007_AI - 6*, *007_AI - 7*, *007_AI - 8* of the *007_AI RemotEye Viewer User Manual*.

Technological Characteristics in common:

Studies and patients search, Display of grayscale and color DICOM images, On-screen presentation of images with several different layouts, Image navigation, Synchronized series navigation for CT and MR, Textual overlays of main image info, Image zooming, Image panning, Window/level contrast manipulation, Image rotation, Image flipping,

Image enhancement, Display of references lines, Cine-playback, Distance measurements, Area measurements, Angle measurements, Graphical annotations, Normal print, DICOM print, Image export, DICOM CD/DVD burning, Report creation and viewing, MPR (Multi-Planar Reconstruction).

Different Technological Characteristics:

- RemotEye Viewer is a software product based on a web-enabled architecture.
  eFilm Workstation is a traditional Windows native desktop application.
- RemotEye Viewer is a multi-platform viewer, it can successfully run on Windows, Mac OS X and Linux.
  eFilm Workstation is a Windows-only software solution.
- RemotEye Viewer is a web-based software designed to integrate with an external DICOM archive. No DICOM files are permanently stored on the client PCs by RemotEye Viewer.
  eFilm Workstation includes an embedded DICOM server, and stores DICOM files locally on the host PC.

These differences don't constitute any new intended use and don't raise new questions of safety and effectiveness.

Testing

RemotEye Viewer is tested according the specifications that are documented in *013-139* and *009_AI Verification and Validation document*.

Testing is an integral part of NeoLogica's software development process as described in *013-126*.

Conclusions

eFilm Workstation and RemotEye Viewer have similar intended use, typical users, functionality and technological characteristics.

RemotEye Viewer provides some different technological characteristics compared to eFilm Workstation; however these differences neither constitute any new intended use, nor raise any questions that affect safety and effectiveness.

Hence RemotEye Viewer is substantially equivalent to eFilm Workstation.